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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Goelet *et al.*

Docket No. 13017-3

Serial No.: 09/258,132

Examiner: Arthur, L.

Filed: February 26, 1999

Group Art Unit: 1655

For: NUCLEIC ACID TYPING BY POLYMERASE  
EXTENSION OF OLIGONULCEOTIDES  
USING TERMINATOR MIXTURES

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Kalow & Springut LLP  
488 Madison Avenue, 19th Floor  
New York, New York 10022

September 27, 2000

Assistant Commissioner for Patents  
Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants submit herewith the following disclosures in accordance with the provisions  
of 37 CFR § 1.97 and § 1.98.

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Certificate of Mailing Under 37 CFR 1.8

I hereby declare that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope  
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9/27/00  
Date

*Franklin S. Abrams*  
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Reg. No. 43,457

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### US PATENT DOCUMENTS

<u>PATENT NO.</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
4,307,189 to Kit	Method for the Quantitative Determination of Terminal Deoxynucleotidyl Transferase in Biological Samples	December 22, 1981
4,563,419 to Ranki et al.	Detection of Microbial Nucleic Acids By a One-Step Sandwich Hybridization Test	January 7, 1986
4,683,195 to Mullis et al.	Process for Amplifying, Detecting and/or Cloning Nucleic Acid Sequences	July 28, 1987
4,883,750 to Whiteley et al.	Detection of Specific Sequences in Nucleic Acids	November 28, 1989
4,968,602 to Dattagupta	Solution-Phase Single Hybridization Assay For Detecting Polynucleotide Sequences	November 6, 1990
5,200,314 to Urdea	Polynucleotide Capture Assay Employing in Vitro Amplification	April 6, 1993
6,013,431 to Soderlund et al.	Method for Determining Specific Nucleotide Variations by Primer Extension in the Presence of Mixture of Labeled Nucleotides and Terminators	January 11, 2000

### FOREIGN PATENT DOCUMENTS

<u>DOCUMENT NO.</u>	<u>TITLE</u>	<u>PUBLICATION DATE</u>
GB 2,202,328	An Improved Method for Assaying of Nucleic Acids, a Reagent Combination and a Kit Therefore	21 September 1988

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<u>DOCUMENT NO.</u>	<u>TITLE</u>	<u>PUBLICATION DATE</u>
WO 86/03782	Improved Sandwich Hybridisation Technique for the Detection of Nucleotide Sequences	3 July 1986
WO 89/09282	Method of Sequencing DNA	5 October 1989
WO 89/10414	Amplified Sequence Polymorphisms (ASPs)	2 November 1989
WO 90/01069	Process for Amplifying and Detecting Nucleic Acid Sequences	8 February 1990
WO 90/06042	Detection and Quantitative Determination of RNA and DNA	14 June 1990
WO 90/11372	Multiplex DNA Diagnostic Test	4 October 1990
WO 91/13075	Method and Reagent for Determining Specific Nucleotide Variations	5 September 1991
WO 92/16657	Method of Identifying a Nucleotide Present at a Defined Position in a Nucleic Acid	1 October 1992
EP 0238332	Liquid Hybridization Method and Kit for Detecting the Presence of Nucleic Acid Sequences in Samples	23 September 1987
EP 0246864	Hybridisation Probes	25 November 1987
EP 0288737	Rapid Hybridization Assay Using Latex- Immobilized Probes	2 November 1988
EP 0317074	Hybridization Method and Reagent Kit Therefor	24 May 1989
EP 0332435	Method of Detecting Nucleotide Sequences	13 September 1989
EP 0333465	Mutation Detection by Competitive Oligonucleotide Priming	20 September 1989

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<u>DOCUMENT NO.</u>	<u>TITLE</u>	<u>PUBLICATION DATE</u>
EP 0357011	Detection and Amplification of Target Nucleic Acid Sequences	7 March 1990
EP 0370694	Diagnostic Kit and Method Using a Solis Phase Capture Means for Detecting Nucleic Acids	30 May 1990
EP 0371437	Method and Reagent Combination for Determining Nucleotide Sequences	6 June 1990
EP 0412883	Fast Process for Detecting and/or Identifying a Single Base on a Nucleic Acid Sequence and Its Applications	13 February 1991

**OTHER DOCUMENTS**

1. Alberts, et al., *Molecular Biology of the Cell, Second Edition*. Garland Publishing, Inc., New York 88-95 (1989).
2. Ballabio et al., "PCR Test for Cystic Fibrosis Deletion", *Nature*, 343:220 (1990).
3. Caskey et al., "Disease Diagnosis by Recombinant DNA Methods", *Science*, 236:1223-1228 (1987).
4. Delius et al., "Separation of Complementary Strands of Plasmid DNA Using the Biotin-Avidin System and Its Application to Heteroduplex Formation and RNA/DNA Hybridizations in Electron Microscopy" *Nucleic Acids Research* 13: 5457-5469 (1985).
5. Ehlen et al., "Detection of Ras Point Mutations by Polymerase Chain Reaction Using Mutation-Specific Inosine-Containing Oligonucleotide Primers", *Biochemical and Biophysical Research Communications*, 160: 441-447 (1989).

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6. Grimberg et al., "A Simple and Efficient Non-Organic Procedure for the Isolation of Genomic DNA From Blood", *Nucleic Acids Research*, 17:8390 (1989).
7. Mitchell et al., "Affinity Generation of Single Stranded DNA Following the Polymerase Chain Reaction: Application to Dideoxy Sequencing", WH 214 *Journal of Cellular Biochemistry Supp.* 13E 18<sup>th</sup> Annual Meeting (1989).
8. Mullis et al., "Specific Synthesis of DNA in Vitro Via a Polymerase-Catalyzed Chain Reaction", *Methods in Enzymology*, 155:335-351 (1987).
9. Nassal et al., "PCR-Based Site-Directed Mutagenesis Using Primers With Mismatched 3' - Ends", *Nucleic Acids Research*, 18:3077-3078 (1990).
10. Newton et al., "Analysis of Any Point Mutation in DNA. The Amplification Refractory Mutation System (ARMS)", *Nucleic Acids Research*, 17:2503-2516 (1989).
11. Riordan et al., "Identification of the Cystic Fibrosis Gene: Cloning and Characterization of Complementary DNA", *Science*, 245:1066-1072 (1989).
12. Rommens et al., "Identification of the Cystic Fibrosis Gene: Chromosome Walking and Jumping", *Science*, 245:1059-1065 (1989).
13. Rossiter et al., "Molecular Scanning Methods of Mutation Detection", *The Journal of Biological Chemistry*, 265:12753-12756 (1990).
14. Running et al. "A Procedure for Productive Coupling of Synthetic Oligonucleotides to Polystyrene Microtiter Wells for Hybridization Capture" *Biotechniques* 8: 276-277 (1990).
15. Signer et al., "DNA Fingerprinting: Improved DNA Extraction From Small Blood Samples", *Nucleic Acids Research*, 16:7738 (1988).
16. Signer et al., "Modified Gel Electrophoresis for Higher Resolution of DNA Fingerprints", *Nucleic Acids Research*, 16:7739 (1988).
17. Smith, "DNA Sequence Analysis by Primed Synthesis", *Methods in Enzymology*, 65:560-581 (1980).
18. Sokolov, B.P. "Primer Extension Technique for the Detection of Single Nucleotide in Genomic DNA" *Nucleic Acids Research* 18: 3671 (1990).

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19. Spitzer et al., "Molecular Defect in Factor IX<sub>Bm Lake Elsinore</sub>", The Journal of Biological Chemistry, 263:10545-10548 (1988).
20. Spitzer et al., "Replacement of Isoleucine-397 by Threonine in the Clotting Proteinase Factor IXa (Los Angeles and Long Beach Variants) Affects Macromolecular Catalysis but not L-tosylarginine Methyl Ester Hydrolysis", Biochem. J. 265: 219-225 (1990).
21. Syvanen et al., "Quantification of Polymerase Chain Reaction Products by Affinity-Based Hybrid Collection," Nucleic Acids Research, 16:11327-11339 (1988).
22. Ware et al., "Genetic Defect Responsible for the Dysfunctional Protein: Factor IX<sub>Long Beach</sub>", Blood, 72:820-822 (1988).

The above documents are also listed on Applicants' PTO 1449 Form which is enclosed for the convenience of the Examiner. A copy of each of the items identified above is submitted with this statement.

EP 0412883, WO 91/13075, WO 92/16657, Sokolov, B.P. Nucleic Acids Research 18: 3671 (1990) and Delius et al. Nucleic Acids Research 13: 5457-5469 (1985) were cited in the supplementary European search report in the prosecution of the corresponding European application. Alberts, et al., *Molecular Biology of the Cell, Second Edition* pp. 88-95 (Garland Publishing, Inc., New York 1989) and Running et al. Biotechniques 8: 276-277 (1990) were cited in a European Office Action in the prosecution of the corresponding European application.

The attorneys for the Applicants take no position on whether or not any item cited above and listed on Form PTO 1449 constitutes prior art against the subject application under any particular provision of Title 35 of the United States Code.

Under 37 CFR § 1.97(c) and § 1.17(p), Attorneys for the Applicants believe the fee for

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this submission is \$240.00. Enclosed is a check for \$240.00. If any additional fee is deemed necessary or overpayment has been made, please charge any payment, or credit any overpayment, to deposit account No. 11-0171.

If there are any questions or comments relating to the present application, the Examiner is respectfully invited to contact Applicants' attorney at the telephone number set forth below.

Respectfully submitted,



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Attorney for Applicants

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